DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

3059 '00 APR 24 A10:33

Kirkland & Ellis
Attention: Frederick Tanne
153 East 53rd St.
New York, NY 10022-4675

APR 14 2000

Docket No. 99P-1150/CP1

Dear Mr. Tanne:

This is in response to your petition filed on April 27, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Norethindrone and Ethinyl Estradiol Chewable Tablets, 0.4 mg/0.035 mg. The listed drug product to which you refer in your petition is Ovcon 35® (Norethindrone and Ethinyl Estradiol) Tablets, 0.4 mg/ 0.035 mg, manufactured by Bristol Myers Squibb.

Your request involves a change in dosage form from that of the listed drug product (i.e., from tablets to chewable tablets). The change you request is the type of change that is authorized under the Act.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

In addition, this petition was evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published in the Federal Register (Pediatric Rule)(63 FR 66632). The agency has determined that your proposed change in dosage form is subject to the Pediatric Rule, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed product in the pediatric population. The safety and efficacy of the listed drug has been established in women of reproductive age and are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of this product before menarch is not indicated.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a dosage form which differs from the dosage form of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form.

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The Agency finds that the change in dosage form for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug product are the same as that of the listed drug product. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol to the Office of Generic Drugs, Division of Bioequivalence for this drug product prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research